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Aquatic therapy for persistent knee pain

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Annually, approximately 25% of people ≥ 55 years old in the United Kingdom (UK) experience persistent knee pain (PKP) which causes disability and reduced quality of life (Peat et al. 2001). Key management strategies comprise self-management advice, weight reduction and exercise (American Academy of Orthopedic Surgeons, National Institute for Health and Care Excellence, 2014; Fransen et al. 2015). Aquatic therapy (AT, exercise in warm water) improves pain and function in long-term musculoskeletal conditions (Barker et al. 2014; Waller et al. 2014). It utilises the properties of water including buoyancy (Harrison & Bulstrode, 1987), resistance (Petrick et al. 2001; Poyhonon et al. 2001) and heat (optimal water temperature 34-45 degrees Celcius (Pool Water Treatment Advisory Group, 2013) (Hall et al. 1990; Becker, 2009) to aid exercise performance.

Evidence from a recent meta-analysis, including eight high and three moderate quality studies (1092 participants), suggest that AT has a short term, small-medium beneficial effect on self-reported pain, joint mobility and function compared to a control group in people with lower limb osteoarthritis (OA) (Waller et al. 2014). When compared to land based exercise, evidence from meta-analyses of six studies (five with a risk of selection bias due to poor of reporting of allocation of concealment; 398 participants) suggests that AT produces similar improvements in self-reported pain and function (Lu et al. 2015). However, the longer term effects of AT are not clear (Cochrane et al, 2005; Lund et al, 2008).

There is no consensus on the most clinical or cost effective dosage or location of delivery for AT for people with PKP (Bartels et al. 2007; Holden et al. 2008). Published AT programmes range from 3x30 minutes weekly sessions for 6 weeks (Foley et al. 2003) to 2x60 minutes weekly sessions for 52 weeks (Lin et al. 2004; Cochrane et al. 2005) with some delivered in public pools at sub-optimal water temperature (Cochrane et al 2005; Wang et al. 2007, 2011). From a societal perspective, a one year AT intervention for people with lower limb OA showed a saving of £123—175/patient/ annum and incremental cost-effectiveness ratios ranged from £3,838 -£5,951 per quality-adjusted life-year in the AT group compared to usual care (Cochrane et al. 2005). However, a survey of 538 practising UK based physiotherapists (77% working in the NHS), suggests that 90% of Physiotherapists provide ≤ 6 sessions of AT for PKP patients (Holden et al. 2008). Therefore, the clinical and cost effectiveness of AT delivered at a dosage and location that reflects contemporary clinical practice needs to be established.

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To inform a definitive trial, this study evaluated the feasibility (participant recruitment, retention and outcome completion rate, adherence and adverse effects) of a randomised controlled trial (RCT) comparing six weekly sessions of AT compared to usual care on self-reported pain, function and general health in adults with PKP.

Methods:

This prospective two arm feasibility RCT received approval from the Joint University College London/University College London Hospital (UCLH) Committees on the Ethics of Human Research Committee Alpha (08/H0715/31) and the UCLH Research and Development Department (08/0103).

Participants and recruitment:

Potentially eligible patients were identified from their physiotherapy referral by a physiotherapist at one inner-city NHS hospital over a 10 week period. The lead researcher screened potential participants for eligibility via the telephone. Eligibility criteria included: adults ≥ 50 years old with self-reported PKP of >3 months duration; knee pain over the past 7 days of $>3/10$ on a Numerical Rating Scale (0=no pain, 10=worst pain imaginable) (Ferreira-Valente et al. 2011) and able and willing to provide informed consent.

Exclusion criteria comprised: self-reported early morning stiffness ≥ 30 minutes; contraindications to AT (Aquatic Therapy Association of Chartered Physiotherapists, 2015); upcoming knee surgery in the next 3 months; physiotherapy, AT or surgery for their PKP in the previous six months; the presence of another condition primarily limiting their mobility. Eligible participants attended one appointment where written informed consent was obtained prior to baseline assessment. The study target sample was 20 participants (Lancaster et al. 2004; Julious 2005; Hertzog, 2008).

Outcome Measures

Feasibility outcomes: the proportion of eligible people willing to enter the study, participant retention rate and outcome completion was recorded by the researcher. The reasons for withdrawal from the

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study (e.g. resentful demoralisation or other factors), adverse effects and attendance at AT sessions was recorded by the treating physiotherapist.

Sociodemographic and clinical outcomes: All sociodemographic characteristics (age (years), gender, Body Mass Index (NHS choices, 2015)) and clinical outcomes were collected at baseline and clinical outcomes were collected at 6 weeks by a researcher who was unaware of participant group allocation.

Self-reported disability was measured using the valid, reliable and responsive Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy et al. 1988; Gentelle-Bonnassies et al. 2000; Angst et al. 2001). This 24-item questionnaire has three subscales; pain (5 items), stiffness (2 items) and function (17 items). Each item is measured on a 5-point Likert scale, with higher scores representing greater symptoms or disability.

Self-reported health status was assessed using the validated Short Form 12 (Jenkinson & Layte, 1997). The physical and mental subscale are each measured by 3 and 5-point Likert scales. Higher scores indicate better health (Gandhi et al, 2001).

Knee pain was assessed using a reliable and valid Visual Analogue Scale (0 -10cm anchors, 0 = no pain, 10 = worst pain imaginable) (McCormack et al. 1988). Participants marked a point on the 10cm line that represented their knee pain at that moment (Bellamy, 1997).

Walking ability was assessed by the 6 minute walk test (American Thoracic Society, 2002). Participants were asked to walk as far as possible around two cones, placed 10 metres apart in a straight corridor, in 6 minutes. The total distance walked (metres) in 6 minutes (6 Minute Walk Distance is reliable (Kennedy et al. 2005) and responsive to change (French et al. 2011) in people with long-term knee conditions.

Protocol

Following baseline assessment, all participants attended one 30 minute individual, self-management education session with a physiotherapist. This comprised: information on the causes of PKP, physical activity/aerobic exercise and knee exercise (e.g. quadriceps strengthening exercises); footwear advice and the use of shock absorbing insoles; activity pacing; pain (e.g. thermotherapy) and weight

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management (Arthritis Research UK, 2005; National Institute for Health and Care Excellence (NICE) (CG177), 2014).

Block randomization with computer generated random block sizes, was conducted and held by a third party unconnected with the study. Following baseline assessment and attendance at the self-management session, participants were randomly assigned to receive either usual care or AT in addition to usual care. The Physiotherapist not involved with the outcome assessment contacted the randomization administrator and informed the participant of their treatment allocation.

Aquatic Therapy Intervention Group

Participants randomised to receive AT, completed 6x30 minutes weekly group sessions of AT delivered by one of two Senior Physiotherapists who had undertaken postgraduate AT training. AT was conducted in a purpose built pool (3x5.6 metres, water temperature 33-35°C). All participants completed a circuit of exercises aimed to increase function (Table 1) (American College of Sports Medicine (2006), The American Geriatrics Society Panel on Exercise and Osteoarthritis (2001)). Participants continued to receive usual medical care as directed by their referring Physician (NICE, 2014).

Usual Care Comparison Group

Participants randomised to the comparison group continued to receive usual medical care e.g. medication, adjunctive therapies (NICE, 2014), as directed by their referring Physician.

Analysis:

Feasibility, sociodemographic and clinical outcomes were summarized using descriptive statistics as appropriate. Effect sizes were calculated using Hedges' *g* (standardized mean difference between outcome scores of AT and usual care group at 6 weeks, adjusted for different sample sizes) (Lenhard & Lenhard, 2016) and categorized as small (0.01–0.19), medium (0.2–0.79) or large (>0.79) (Cohen, 1998). Statistical analysis was performed on SPSS (version 12.0.1, SPSS Inc. Chicago).

Results:

Thirty nine patients were screened for eligibility during the 10 week recruitment period. Eighteen people met the eligibility criteria but four declined to participate due to other commitments (insufficient time) (2 males and 2 females) (Figure 1)). 14 participants ((mean (SD) age 63 (7.5) years, all female) were randomised (n=7 AT, n=7 comparison group, 78% recruitment rate). 13 participants completed the study. One participant withdrew from the study after randomisation due to their allocation to the comparison group (resentful demoralization) (Figure 1).

At baseline there were no substantial differences between the groups in any sociodemographic or clinical outcomes (Table 2) or between the participant that withdrew and those who completed the study.

Attendance at the AT was 98%. One participant did not attend one session (unrelated illness). No adverse effects were reported. All clinical measures were fully completed by the participants who completed the study.

At 6 weeks, small to medium effects were found in all clinical outcomes, favouring AT (Table 2).

Discussion:

This study demonstrated that a two arm RCT evaluating six, weekly sessions of AT compared to usual care was feasible and that our AT programme was well tolerated by people with PKP. The improvement in outcomes following AT is promising and suggests that a definitive RCT is warranted.

Our recruitment rate was higher than most previous studies of AT (Foley et al. 2003, Fransen et al. 2007) and implies that recruiting patients with PKP from NHS physiotherapy departments is feasible. Our study retention rates are good (93%), concurring with other work (Waller et al. 2014). High study retention rates are important because attrition of participants may threaten validity of RCTs, produce bias and limit statistical validity by reducing the power to detect true between group differences (Zweben et al.

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2009). Only one of our participants withdrew following randomisation to the comparison group but strategies, such as incentives, to minimise resentful demoralisation, should be considered (Adamson et al. 2006).

Our participants had high attendance at AT (98%,) which compares favourably with other studies (Foley et al. 2003; Fransen et al. 2007; Hinman et al. 2007; Lund et al. 2008; Wang et al. 2011) suggesting participants found the duration and intensity of our programme acceptable and tolerable, as there were no reported adverse effects.

Whilst our study was not powered to detect a change in any clinical variables, our findings are promising and reflect the findings of a meta-analysis of AT for other long-term musculoskeletal conditions (Barker et al. 2014) and lower limb OA (Waller et al. 2014) suggesting our programme warrants further investigation.

Our study has several strengths. Our programme is based on clinical guidelines and reflects contemporary UK practice, unlike other studies (Cochrane et al. 2005; Fransen et al. 2007; Silva et al. 2008; Wang et al. 2011). Key objective and self-reported clinical variables for PKP were included and were fully completed by our female participants, who had sociodemographic and clinical characteristics which are typical for participants with PKP entered into exercise studies (Jordan et al. 1996; Hurley et al. 2007), suggesting they did not find the assessment burdensome. Anecdotal feedback from clinicians and participants suggests that the protocol was feasible and that AT was acceptable to participants, although, formal qualitative exploration in a mixed method study is required.

This study has several limitations. We did not meet our target sample (n=20), although our recruitment rate was typical for studies of AT (5-6 participants /month (Foley et al. 2003; Lund et al. 2008). Only women were enrolled onto our study reflecting evidence from a meta-analysis evaluating the effectiveness of AT for lower limb OA, which reported that 73% of participants were female (Waller et al. 2014). Relatively few key measures were included in our study, similar to previous research (Foley et al. 2003; Cochrane et al. 2005; Silva et al. 2007; Lund et al. 2008; Gill et al. 2009; Wang et al. 2011) and no assessments were conducted after 6 weeks, so the impact of a longer study duration could not be

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captured. No formal qualitative data exploring the acceptability and experience of AT and our study protocol was collected.

This study will inform our definitive trial design. Dedicated research staff will be employed to screen referrals which may increase the identification and recruitment of potential participants. Other outcomes (e.g. quality of life, cost utility) and assessment time points (e.g. 6 and 30 months) will be included to more completely capture the effect of AT in the longer term, similar to other studies in PKP (Hurley 2007). Our AT programme will be offered at a range of times (e.g. evening) to increase accessibility and acceptability to males and others with life commitments. Records of other therapies prescribed during the trial and mixed research method will be used to formally explore the acceptability and experience of AT and the study to participants and clinicians.

Conclusion:

Our study showed that an RCT of a clinically practicable AT programme for people with PKP was feasible. It had typical recruitment, retention and outcome completion rate and was well tolerated by women with PKP. This suggests that our programme warrants further investigation and, if effective, could inform the delivery of AT for people with PKP in practice.

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Table 1: Circuit of Aquatic Therapy exercises for people with Persistent Knee Pain
Warm up: Walking forwards, backwards, sideways
<p>In standing:</p> <ul style="list-style-type: none">• Hip and knee extension buoyancy resisted• Knee flexion buoyancy assisted (hip in neutral)• Knee extension buoyancy resisted (hip in neutral)• Hip abduction• Single leg stands +/- throw and catch ball• Squats progressing to single leg squats• Lunges• Quadriceps, hamstring and gastrocnemius muscle stretch 2x30seconds <p>In sitting:</p> <ul style="list-style-type: none">• Knee buoyancy assisted knee extension, buoyancy resisted knee flexion. Progressing to use flippers for resistance <p>Step:</p> <ul style="list-style-type: none">• Step up• Step down• Step up and over <p>Supine supported by woggle/floats:</p> <ul style="list-style-type: none">• Cycling, progression by incorporating flippers for resistance• Hip extension buoyancy resisted
<p>Dosage and Progression:</p> <ul style="list-style-type: none">• To be performed at self-perceived 'somewhat hard' intensity on BORG scale (Dawes et al.

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2005)

- Progressed when rate of perceived exertion dropped below 'somewhat hard' by:
 - Increased repetition per set (8-12) or number of sets per exercises (1-3) (Ratamess et al. 2009)
 - Increasing speed to increase resistance (for example 1 repetition over 2 seconds progressed to 1 repetition over 1 second) in order to maintain rate of perceived exertion of at least 'somewhat hard'
 - Increased buoyancy aids to increase resistance
 - Move to shallower water to reduce effects of buoyancy

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Table 2. Sociodemographic and clinical outcome measures following 6 weeks of Aquatic Therapy or usual care

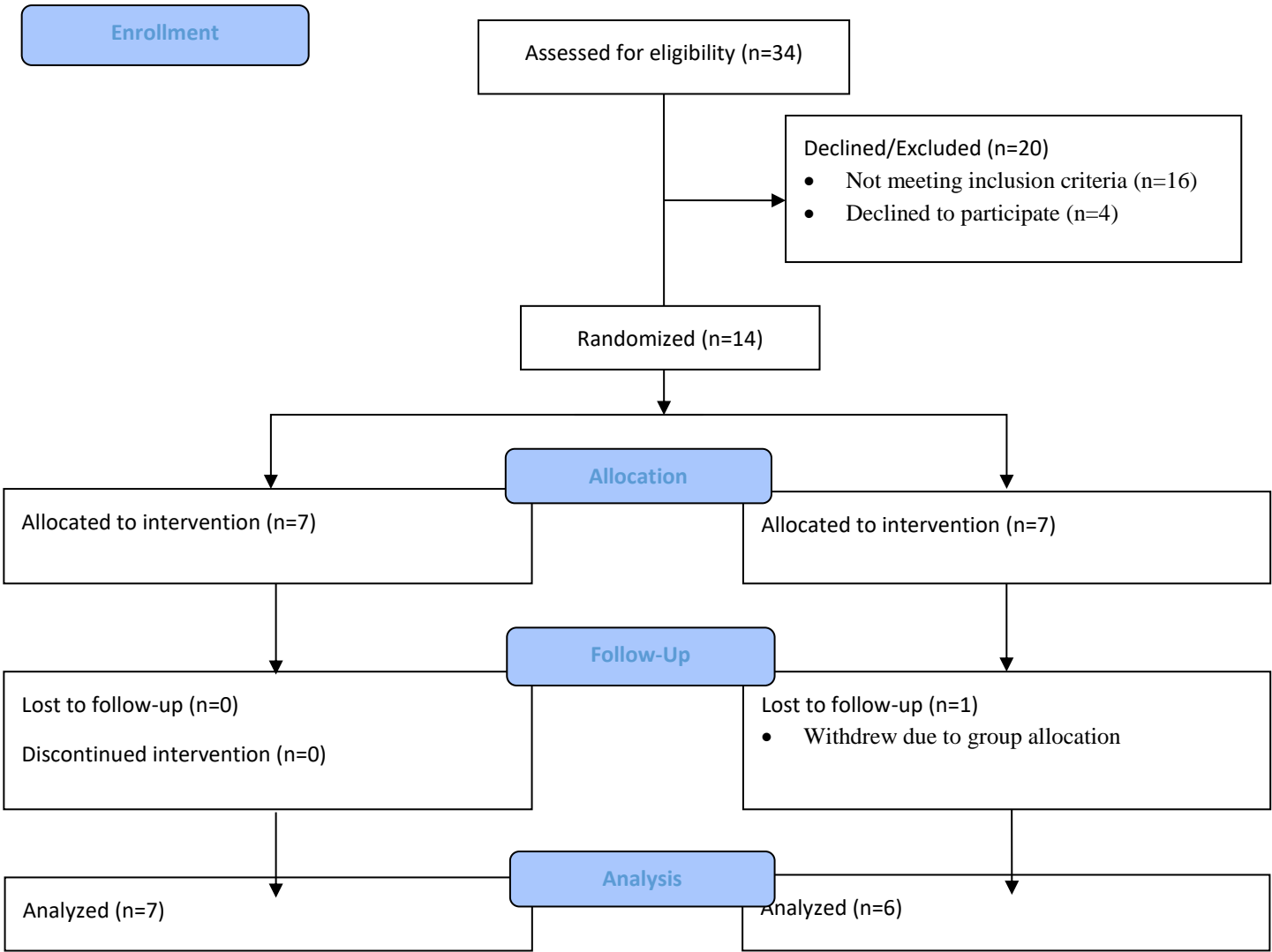
	Aquatic therapy			Comparison Group			
Outcomes	Baseline	6 weeks	Change	Baseline	6 weeks	Change	Effect size
							Hedges' <i>g</i>
Age (years)	64.3 (8.7)			62.3 (6.6)			
Weight (Kg)	78.1 (17.9)			88.1 (26.5)			
Height (m)	1.54 (0.04)			1.59 (0.06)			
BMI	32.4 (6.2)			34.6 (10.3)			
WOMAC – total	82.0 (19.1)	64.3 (18.2)	-17.7 (14.9)	65.0 (20.4)	67.6 (22.5)	2.6 (9.6)	0.16
WOMAC- Pain	16.7 (4.3)	11.6 (2.4)	- 5.1 (4.2)	14.3 (4.2)	14.6 (5.5)	0.3 (1.9)	0.73
WOMAC- stiffness	7.1 (1.3)	5.3 (2.3)	-1.9 (2.7)	6.6 (1.9)	6.9 (2.12)	0.3 (1.1)	0.72
WOMAC- function	58.1 (14.7)	47.4 (14.4)	-10.7 (8.9)	44.1 (16.7)	46.1 (16.3)	2.0 (9.6)	0.09
SF12 – mental	42.9 (16.8)	51.0 (12.0)	8.2 (9.2)	43.4 (13.1)	44.6(9.9)	1.2 (5.2)	0.58
SF 12 physical	33.4 (8.7)	37.7 (13.1)	4.3 (12.8)	34.6 (10.5)	34.6 (10.8)	0.01 (4.1)	0.26
VAS pain (cm)	7.9 (2.1)	4.5 (2.8)	-3.4 (3.9)	5.63 (2.6)	6.1 (2.5)	0.5 (1.1)	0.60
6MWD (m)	238.6 (85.5)	287.1 (63.2)	48.6 (58.1)	247.1 (98.4)	270.0 (74.8)	22.9 (42.7)	0.25

BMI – Body Mass Index, WOMAC - Western Ontario and McMaster Universities Osteoarthritis Index, SF12 - Short Form-12, 6MWD - Six minute walk distance and VAS - Visual Analogue Scale. All data presented as Mean (Standard Deviation)

Effect size: standardized mean difference between outcome scores of AT and usual care group at 6

weeks

Figure 1. Flow of participants



Aquatic therapy for persistent knee pain